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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,694	12/28/2001	Steven D. Kruse	1416.49US01	2324
22865	7590	06/18/2004	EXAMINER	
ALTERA LAW GROUP, LLC 6500 CITY WEST PARKWAY SUITE 100 MINNEAPOLIS, MN 55344-7704			SWEET, THOMAS	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/034,694

Applicant(s)

KRUSE ET. AL.

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-33 is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-21 and 23-26 is/are rejected.
- 7) ☒ Claim(s) 16-18, 22, and 27-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date: \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

***Claim Rejections - 35 USC § 102*** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-7, 9-10, 14-15, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al (US 5899937). Goldstein et al discloses test apparatus and method for testing a stented heart valve with a flexible membrane (fig. 2) by applying backwards pressure (Col 10, lines 44-47) to the valves in the flow blocking position. Based of figure 2 the valve does not open fully in the forward flow direction more than about 80% of the cross sectional area. The test apparatus (fig. 3) comprises a cyclic pressure applicator (pump chamber) a conduit connected to the pressure applicator and a stent test structure mounted in the conduit (fig. 2).

With regard to claim 4, Column 10, lines 44-47 states that the peak pressure would be 120 mm Hg.

With regard to claim 14, see the abstract.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 11-13, 19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al in view of Pietsch et al (US 4778461). Goldstein et al discloses a test apparatus and method for testing a stented heart valve as discussed above. However, Goldstein et al remains silent as to the heart valve stent having commissure posts and does not disclose the heart valve membrane being made of polyurethane or silicone integrally cast with the stent. Heart valves having commissure posts and having a membrane of polyurethane or silicone integrally cast with the stent are well known in the art of heart valves as demonstrated by Pietsch et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to test the stent of Pietsch et al in the test apparatus of Goldstein et al in order to perform tests on the valve of Pietsch et al.

With regard to claim 5, the commissure post would inherently deflect inward the equivalent amount that they would when subject to a pulse duplicator at physiological condition, since the test apparatus functions at physiological condition.

Claims 8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al in view of Eberhardt (US 5176153). Goldstein et al discloses a test apparatus and method for testing a stented heart valve as discussed above. However, Goldstein et al does not

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disclose testing at a frequency of from about 1000 to about 6000 cycles per minute. Eberhardt teaches another a test apparatus and method for testing a stented heart valve which includes testing at a frequency of up to 400 cycles per second (Col 6 lines 29-43, i.e. up to 24000 cycles per minute) for the purpose of accelerated wear and fatigue testing. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the test apparatus of Goldstein et al in order to test at a frequency of up to 24000 cycles per minute (including 1000-6000 cycles per minute) as taught by Eberhardt in order to perform accelerated wear and fatigue tests.

### *Response to Arguments*

Applicant's arguments filed 5/24/04 regarding claims 1-15, 19-21, 23-26 and the Goldstein reference have been fully considered but they are not persuasive. The applicant defines "does not fully open" with respect to the inflow edge of the stent. The nozzle of Goldstein et al tapers to about 80% of the full open lumen, so a valve installed in the nozzle when fully open against the walls of the nozzle would only open about 80% of the full open lumen. Goldstein et al does state that the valve is fully open but that is against the wall of the nozzle and is less than fully open with respect to the inflow edge of the stent. As "does not fully open" is defined by the applicant, Goldstein et al anticipates the rejected claims.

Applicant's arguments filed 5/24/04 regarding claims 5 and 19-21 and the Pietsch reference have been fully considered but they are not persuasive. Applicant is trying to arbitrarily argue which portion of the integrally cast (unitary) heart valve of Pietsch is the stent portion. Since, the Pietsch heart valve is also integrally case and is of the same shape (i.e. components) and function as the applicant, this argument is superfluous

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*Allowable Subject Matter*

Claims 29-33 are allowed.

Claims 16-18, 22 and 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

This is a request for continued examination. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018.

The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tjs

  
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